Company:	Summit Technology, Inc.
Device:	Summit Krumeich-Barraquer Microkeratome
510(k):	K980675
Date Cleared:	December 22, 1998
Company:	Plancon Instruments
Device:	Microlamellar Keratome-Evolution Power Unit
510(k):	K980924
Date Cleared:	April 15, 1998
Company:	American Medical Optics
Device:	Barraquer-Krumeich Refractive Set
510(k):	K860001
Date Cleared:	February 4, 1986

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The IntraLase 600C Laser Keratome is a precision ophthalmic surgical laser designed for use in performing lamellar corneal resections. The materials, basic scientific concepts and physical properties of the IntraLase 600C have been cleared for a different indication for use under K993153.

5. Statement of intended use:

The IntraLase 600C Laser Keratome is indicated for patients undergoing lamellar resection of the cornea, including keratoplasty and corneal harvesting, microlamellar keratoplasty, keratomileusis *in situ,* and microlamellar keratoplasty or keratomileusis *in situ* for the correction of myopia and hyperopia. These additional intended uses are identical to those of the predicate devices.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

The technological characteristics of the IntraLase 600C Laser Keratome have already been cleared under K993153 for lamellar corneal resections. The design, materials, and characteristics of the laser keratome are the same irrespective of the indication for use.

The laser scanning pattern and the related software controls have been customized to allow for the additional indications for use.

7. Brief summary of nonclinical tests and results:

The IntraLase 600C Laser Keratome has undergone testing and is in compliance with applicable safety standards. In addition, the IntraLase 600C was found to perform equivalently to the predicate devices, with respect to the creation of corneal resections in extensive *ex vivo* and *in vivo* studies. Thus, the IntraLase 600C Laser Keratome and the predicate devices have similar safety, effectiveness or performance profiles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2001

Intralase Corporation
c/o Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
18732 Saginaw
Irvine, California 92612

Re: K002890
Trade/Device Name: IntraLase 600C Laser Keratome
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX, HNO
Dated: July 10, 2001
Received: July 12, 2001

Dear Dr. Gordon:

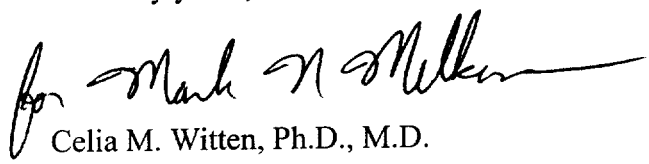
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002890

Device Name: IntraLase 600C Laser Keratome

Indications for Use:

The IntraLase 600C Laser Keratome is an ophthalmic surgical laser indicated for use in:

Lamellar keratoplasty and corneal harvesting
Keratomileusis *in situ* for the correction of myopia

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use ✓ OR Over-The-Counter Use ____
(Optional Format 1-2-96)

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002890